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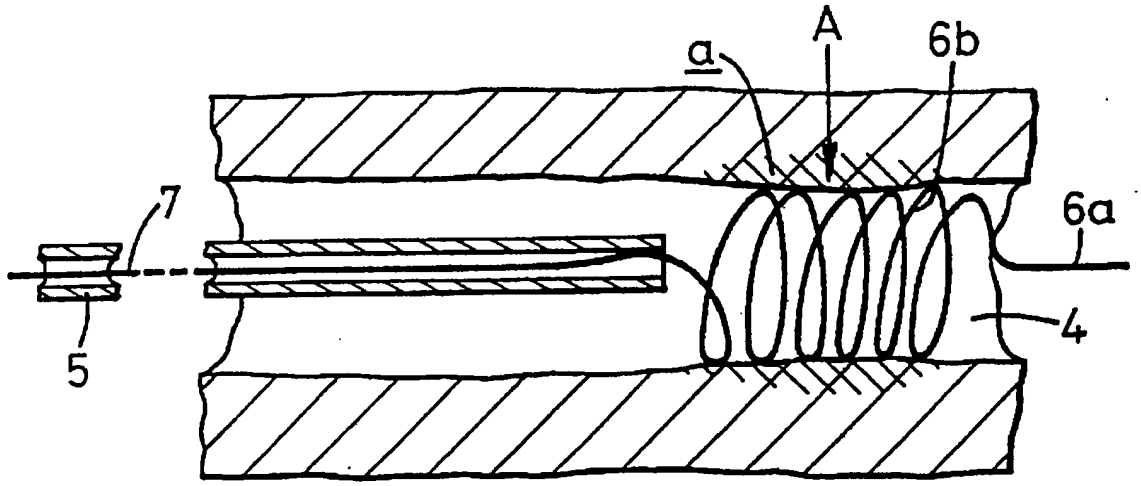
(54) Title: ANGIOPLASTY STENT FOR USE WITH A CATHETER



(57) Abstract

A "stent" (6) for use in conjunction with a balloon type catheter (2), in order to shore-up tissue (A) which has been damaged by use of the balloon type catheter (2), is characterised in that it comprises a coil-like spring member which is contained in a substantially linear stressed condition within the catheter (2) for transport to the diseased area (A) and which when released from the catheter (2) adopts a coiled configuration (6b) to hold the damaged tissue (A) in place whilst at the same time allowing blood flow.

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Angioplasty stent for use with a catheter

The present invention relates to catheters for insertion into the human body.

There are many designs of catheters for different medical purposes and the present invention is particularly concerned with the use of so-called balloon-type catheters which are used to flatten the interior of a diseased artery in order to increase the internal cross-section of the artery at the point where it would otherwise be constricted by a diseased area or plaque.

A known treatment involves inserting a balloon catheter into the artery, expanding the balloon at the point of the diseased area to thus compress that diseased area into the wall of the artery. The balloon is then deflated and the catheter withdrawn from within the patient.

Whilst in many cases the compressed diseased area will remain compressed and thus leave the artery relatively open for the flow of blood, there are occasions when upon extraction of the deflated balloon portions of the diseased area fall back into the passageway of the

artery to thereby continue to obstruct it whilst still being connected to the internal wall of the artery.

There are a number of known approaches to dealing with this particular problem.

One approach is to use a so-called "stent" which consists essentially of a fine wire element, made of stainless steel or the like, which is used to, as it were, shore-up the above-mentioned projecting diseased portions.

There are a number of known ways in which the so-called "stent" can be inserted into the artery and brought into an operative position in relation to the diseased portion.

Clearly, the "stent" has to be in a collapsed state in order to enable it to be inserted into the artery. There are different ways in which the collapsed "stent" is then expanded, once it is in the desired position, in order to shore-up the aforesaid diseased portion.

One way of expanding the "stent" is to mount it on a balloon which can be inflated by remote control from the end of the catheter which is outside the patient's body. Such a "stent" is sometimes referred to as being "balloon expandable".

An alternative method employs a so-called "self-expanding stent". In this arrangement, the "stent" is collapsed onto a centre tube under tension and held in the collapsed state by a sleeve. The sleeve containing the collapsed "stent" is inserted into the patient's artery to bring the "stent" into the vicinity of the diseased area. The sleeve is then withdrawn to expose the collapsed "stent" which can thus expand as a result of its having been collapsed under tension and contained by the sleeve.

With these known arrangements, the expanded "stent" pushes the aforementioned diseased portions back into the wall of the artery and holds them there. The "stent" remains permanently in the patient's artery.

The present invention is concerned with providing an alternative to the above known arrangements, which alternative will be simpler to use, have a wider application of use and in addition have the advantage

of not leaving the "stent" permanently embedded in the artery wall.

According to the present invention, a catheter for flattening the interior wall of an artery or other organ includes the following combination of features:

a) a balloon catheter or simple catheter tube;

b) a "stent" contained within a) in a stressed collapsed condition, the tube a) and "stent" being movable axially with respect to one another to progressively bring the "stent" outside the tube, the "stent" then being radially expandable;

characterised in that the "stent" comprises an element which in its contracted state is substantially linear to fit in the catheter tube but which when free of the catheter tube adopts an expanded hollow configuration whereby it can press against the interior surface of an artery but still allow blood flow through the artery.

How the invention may be carried out will now be

described in more detail, but by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a partial cross-sectional view showing the use of a prior art catheter for flattening a diseased area formed on the inside of a patient's artery;

Figure 2 is a view similar to Figure 1 showing the insertion of one embodiment of a catheter according to the present invention into the patient's artery shown in Figure 1;

Figure 3 is a view similar to Figure 2 showing a later stage of the insertion of the embodiment shown in Figure 2;

Figure 4 is a view similar to Figures 2 and 3 showing the final stage of the insertion of the "stent" of Figure 2 with it in its operative position within a patient's artery; and

Figure 5 is a view similar to Figure 2 showing the insertion of a second embodiment of a catheter according to the present invention into the patient's artery shown in Figure 1.

Figure 1 shows the use of a known type of so-called balloon catheter used to flatten a diseased area within a patient's artery.

The artery 1 has a diseased area indicated by A which has the effect of restricting blood flow through the artery.

In order to improve the blood flow, it is known to insert a catheter 2 provided with a balloon device 3, into the artery 1 and to inflate the balloon device (as illustrated in Figure 1) in order to press the diseased area A back into the wall of the artery 1. The balloon is inflated by feeding liquid into it through a lumen formed in the catheter or through an annular space formed around the outside of the catheter.

The method of inserting the balloon catheter into the artery involves the use of a lead wire 3a. The lead wire 3a is first inserted into the artery, the catheter carrying the balloon then being slid along the wire to the position shown. Alternatively, the lead wire 3a could be incorporated into the catheter.

In most cases such action will have the desired effect of more or less permanently compressing the diseased area A into the wall of the artery 1 and thus increasing the cross-section of the artery at that point to enable blood flow to be improved. However, in a minority of cases, although the majority of the diseased portion A may be so compressed, fragments of the diseased portion A, shown as a in Figure 2, fall back, as it were, into the artery passage 4 when the balloon 3 is deflated and withdrawn.

It is with this problem that the present invention is concerned.

A catheter according to one embodiment of the present invention is shown in Figure 2 and comprises a tube 5 containing a "stent" element 6 carried on the distal end of a very thin wire 7 which extends to the other proximal end of the catheter tube 5. The preferred material for the "stent" element 6 and the wire 7 is stainless steel, tantalum, or a nylon type polymer.

In the position shown in Figure 2, the "stent" element 6 is in a stressed condition where it lies substantially linearly within the catheter tube 5. A substantially straight lead portion 6a of the "stent"

is at the extreme distal end to assist the insertion of the catheter into the patient's artery. This lead portion 6a is typically 1 to 3 cm long.

The catheter tube 5 containing the "stent" element 6 is inserted into the patient's artery 1 as illustrated in Figure 2.

Further axial movement of the catheter 5 towards the right, in the drawings, brings the distal end of the catheter tube 5 into the vicinity of the diseased area A, as shown in Figure 3. In that position the proximal end of the wire 7 is moved to the right (as viewed in the drawings) in order to in turn move the "stent" element 6 out of the distal end of a catheter tube 5.

As soon as any further portion of the "stent" element 6 becomes free of the catheter tube 5, as the latter is slid to the left as viewed in the drawings, its built in stress will cause it to adopt a coiled configuration as shown at 6b in Figure 3, due to the stress previously built into the wire comprising the "stent".

The diameter of the coiled configuration is

substantially larger than the internal diameter of the catheter tube 5.

In practice "stents" having a range of diameters would be provided for different applications. Typically the range could be of 2 to 4.5 mm diameter in 0.5 mm steps.

The catheter tube 5 can then be withdrawn from the patient's artery 1 to leave the "stent" element 6 in the position shown in Figure 4, in which the expanded coils of the "stent" element 6 hold the portions a of the diseased area A back against the wall of the artery 1.

As indicated earlier, a range of different sizes of "stent" would be provided, both in terms of coil diameter and axial length of the coiled portion. Typically the latter could be in the range 1 to 3 cm.

Because of the fine diameter of the wire making up the "stent" element 6 and because of the expanded diameter of its coils, the "stent" 6 presents the minimum resistance to the flow of blood through the artery, whilst at the same time ensuring that the diseased

area A and in particular the portions a , do not impede that flow.

Figure 5 shows a second embodiment of the present invention in which the coiled temporary "stent" 6 is used in conjunction with a balloon catheter 3 of the type already shown in Figure 1. In other words, the "stent" is incorporated into such a catheter instead of being used completely separately from the balloon catheter.

With this arrangement the balloon catheter would be operated, as shown in Figure 1, to flatten the diseased portion A of the wall of the artery 1. The balloon would then be deflated and withdrawn together with the catheter tube to thus expose or release the coiled "stent" 6 to enable it to adopt the expanded configuration shown in Figures 3 and 4.

The "stent" of the present invention, unlike those of the prior art, is not intended to be permanently left in the patient's artery.

With the designs of "stent" described above and illustrated in the drawings, it is possible to effect a quick temporary, as it were repair, to the internal

wall of the artery 1 whilst either the tissue of the artery heals or whilst a further treatment of the condition is prepared.

Although a specific configuration and construction of "stent" has been illustrated and described, variations could be made within the scope of the present invention.

The essence of the present invention is that, unlike known "stents", the operative element of the "stent" relies on its in-built "memory" to return from its collapsed constrained configuration to its relatively unstressed expanded configuration i.e. a separate mechanism for expanding the "stent" is not required. Within this concept, clearly a number of constructions of "stent" could be employed, of which that illustrated is only one.

CLAIMS:

1. A catheter for flattening the interior wall of an artery or other organ includes the following combination of features:

a) a balloon catheter or simple catheter tube;

b) a "stent" contained within a) in a stressed collapsed condition, the tube a) and "stent" being movable axially with respect to one another to progressively bring the "stent" outside the tube, the "stent" then being radially expandable;

characterised in that the "stent" comprises an element which in its contracted state is substantially linear to fit in the catheter tube but which when free of the catheter tube adopts an expanded hollow configuration whereby it can press against the interior surface of an artery but still allow blood flow through the artery.

2. A catheter as claimed in claim 1, in which the operative element of the "stent" comprises a coil spring.

3. A catheter as claimed in claim 2, in which the coil spring is formed on one end of a fine wire adapted to pass the length of the catheter tube.

4. The "stent" as defined in any one of claims 1 to 3 separate from the catheter.

5. A catheter substantially as hereinbefore described with reference to and as shown in Figures 2 to 4 of the accompanying drawings.

6. A "stent" substantially as hereinbefore described with reference to and as shown in Figures 2 to 4 of the accompanying drawings.

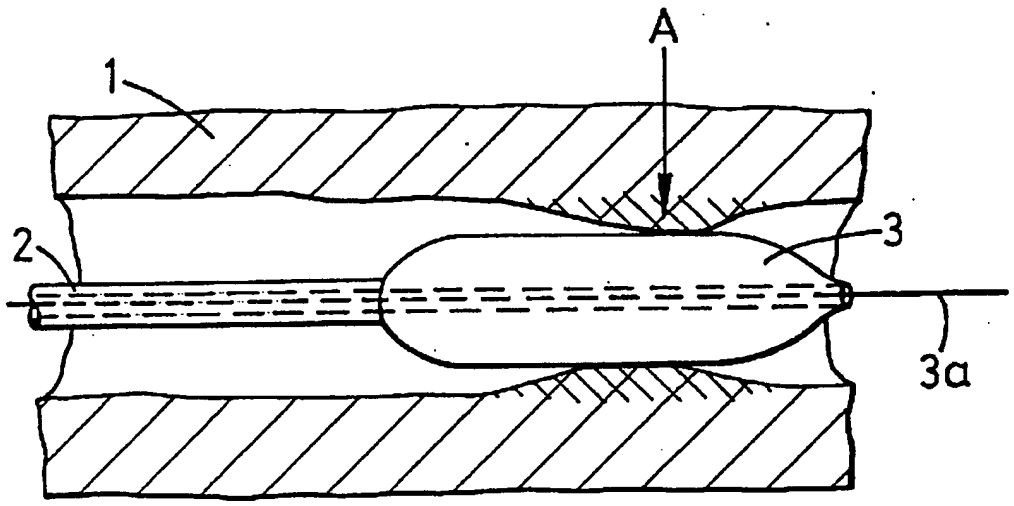

FIG.1

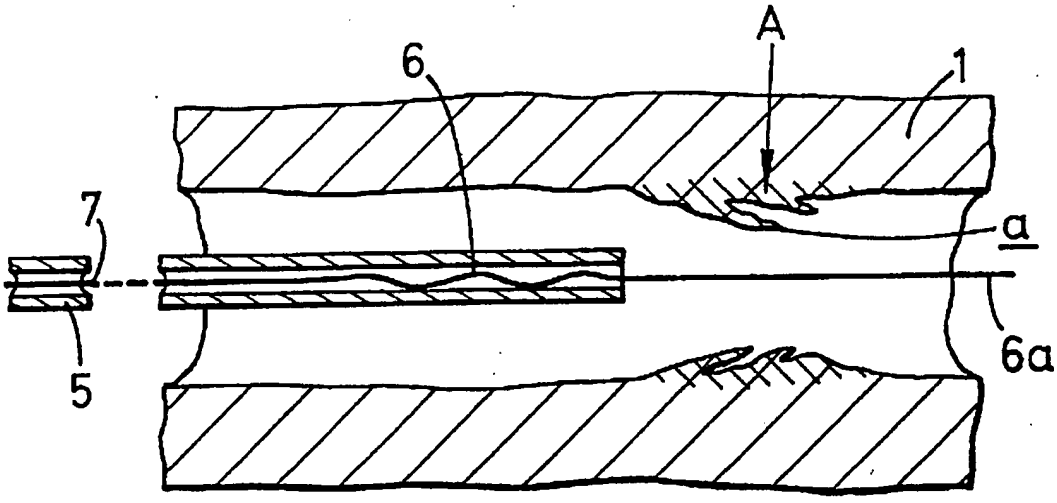

FIG.2

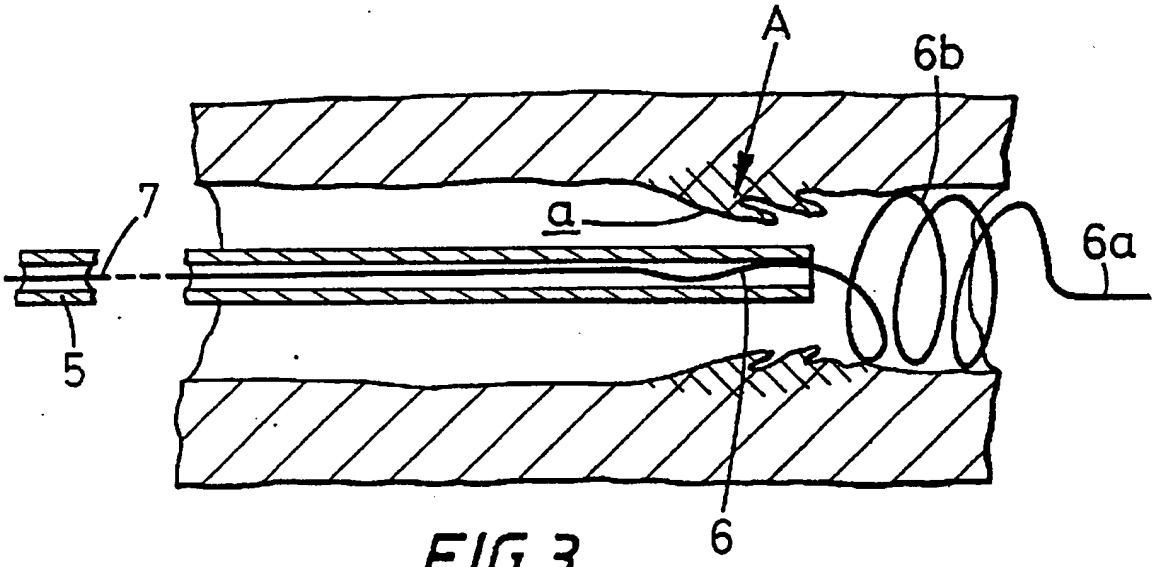

FIG.3

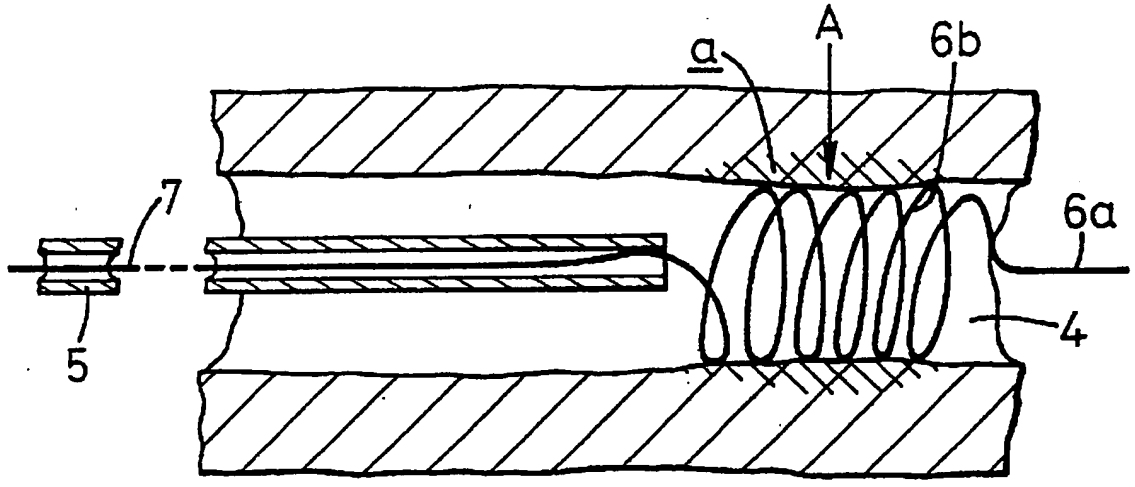

FIG.4

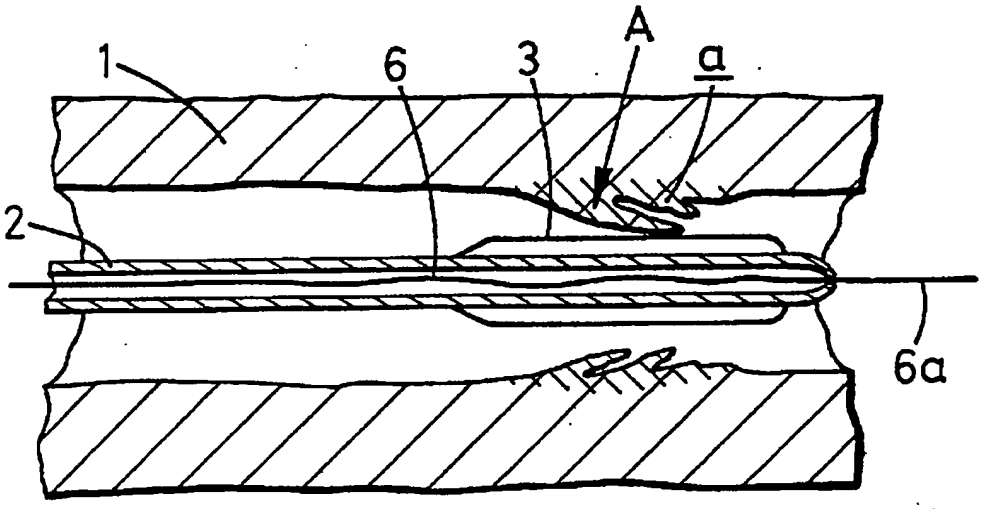

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/01805

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 F 2/06

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 F, A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	WO, A, 83/03752 (WALLSTEN) 10 November 1983 see abstract; page 14, line 18 - page 15, line 24; page 18, line 20 - page 20, line 28; figures 1,10,11 --	1-4
Y	EP, A, 0119688 (BALKO) 26 September 1984 see abstract; page 13, lines 3-18; figures 7,8 --	1-4
A	EP, A, 0201466 (MEDINVENT S.A.) 12 November 1986 see abstract; figures 1,5 --	1

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* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22nd February 1991	05. 04. 91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	F.W. HECK

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	WO, A, 87/04935 (FISCHELL et al.) 27 August 1987 see abstract; page 7, lines 1-8; figure 3	1-3
A	US, A, 4503569 (DOTTER) 12 March 1985 see abstract; column 4, lines 8-40; figures 3-6	2
A	US, A, 4856516 (HILLSTEAD) 15 August 1989 see abstract; column 4, line 66 - column 3, line 19; figure 1	2

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 5.,6. because they relate to subject matter not required to be searched by this Authority, namely:

see PCT rule 6.2(a)

2. [ ] Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9001805 SA 42167

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 26/03/91
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A- 8303752	10-11-83	SE-B-	445884	28-07-86
		AU-A-	1518683	21-11-83
		CA-A-	1239755	02-08-88
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		JP-T-	59500652	19-04-84
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		SE-A-	8202739	31-10-83
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		SE-A-	8501762	11-10-86
		US-A-	4760849	02-08-88
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US-A- 4503569	12-03-85	None		
US-A- 4856516	15-08-89	EP-A-	0378151	18-07-90